

108TH CONGRESS
1ST SESSION

S. 1974

To make improvements to the Medicare Prescription Drug, Improvement,
and Modernization Act of 2003.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 25, 2003

Mr. DASCHLE introduced the following bill; which was read twice and referred
to the Committee on Finance

A BILL

To make improvements to the Medicare Prescription Drug,
Improvement, and Modernization Act of 2003.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Preservation
5 and Drug Price Fairness Act”.

6 **SEC. 2. AUTHORITY TO NEGOTIATE PRICES.**

7 Subsection (i) of section 1860D–11, as added by sec-
8 tion 101 of the Medicare Prescription Drug, Improvement,
9 and Modernization Act of 2003, is repealed.

1 **SEC. 3. REPEAL OF COMPARATIVE COST ADJUSTMENT**
2 **(CCA) PROGRAM.**

3 Subtitle E of title II of the Medicare Prescription
4 Drug, Improvement, and Modernization Act of 2003, and
5 the amendments made by such subtitle, are repealed.

6 **SEC. 4. PHARMACEUTICAL MARKET ACCESS.**

7 (a) IMPORTATION OF PRESCRIPTION DRUGS.—Sec-
8 tion 804 of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 384) is amended—

10 (1) in subsection (a)—

11 (A) by striking “The Secretary” and in-
12 serting “Not later than 180 days after the date
13 of the enactment of the Medicare Prescription
14 Drug, Improvement, and Modernization Act of
15 2003, the Secretary”; and

16 (B) by striking “pharmacists and whole-
17 salers” and inserting “pharmacists, wholesalers,
18 and qualifying individuals”;

19 (2) in subsection (b)—

20 (A) by amending paragraph (1) to read as
21 follows:

22 “(1) require that each covered product imported
23 pursuant to such subsection complies with sections
24 501, 502, and 505, and other applicable require-
25 ments of this Act; and”;

1 (B) in paragraph (2), by striking “, includ-
 2 ing subsection (d); and” and inserting a period;
 3 and

4 (C) by striking paragraph (3);

5 (3) in subsection (c), by inserting “by phar-
 6 macists and wholesalers (but not qualifying individ-
 7 uals)” after “importation of covered products”;

8 (4) in subsection (d)—

9 (A) by striking paragraphs (3) and (10);

10 (B) in paragraph (5), by striking “, includ-
 11 ing the professional license number of the im-
 12 porter, if any”;

13 (C) in paragraph (6)—

14 (i) in subparagraph (C), by inserting
 15 “(if required under subsection (e))” before
 16 the period;

17 (ii) in subparagraph (D), by inserting
 18 “(if required under subsection (e))” before
 19 the period; and

20 (iii) in subparagraph (E), by striking
 21 “labeling”;

22 (D) in paragraph (7)—

23 (i) in subparagraph (A), by inserting
 24 “(if required under subsection (e))” before
 25 the period; and

1 (ii) by amending subparagraph (B) to
2 read as follows:

3 “(B) Certification from the importer or
4 manufacturer of such product that the product
5 meets all requirements of this Act.”; and

6 (E) by redesignating paragraphs (4)
7 through (9) as paragraphs (3) through (8), re-
8 spectively;

9 (5) by amending subsection (e) to read as fol-
10 lows:

11 “(e) TESTING.—

12 “(1) IN GENERAL.—Subject to paragraph (2),
13 regulations under subsection (a) shall require that
14 testing referred to in paragraphs (5) through (7) of
15 subsection (d) be conducted by the importer of the
16 covered product, unless the covered product is a pre-
17 scription drug subject to the requirements of section
18 505B for counterfeit-resistant technologies.

19 “(2) EXCEPTION.—The testing requirements of
20 paragraphs (5) through (7) of subsection (d) shall
21 not apply to an importer unless the importer is a
22 wholesaler.”;

23 (6) in subsection (f), by striking “or designated
24 by the Secretary, subject to such limitations as the

1 Secretary determines to be appropriate to protect
2 the public health”;

3 (7) in subsection (g)—

4 (A) by striking “counterfeit or”; and

5 (B) by striking “and the Secretary deter-
6 mines that the public is adequately protected
7 from counterfeit and violative covered products
8 being imported pursuant to subsection (a)”;

9 (8) in subsection (i)(1)—

10 (A) by amending subparagraph (A) to read
11 as follows:

12 “(A) IN GENERAL.—The Secretary shall
13 conduct, or contract with an entity to conduct,
14 a study on the imports permitted pursuant to
15 subsection (a), including consideration of the
16 information received under subsection (d). In
17 conducting such study, the Secretary or entity
18 shall evaluate the compliance of importers with
19 regulations under subsection (a), and the inci-
20 dence of shipments pursuant to such sub-
21 section, if any, that have been determined to be
22 misbranded or adulterated, and determine how
23 such compliance contrasts with the incidence of
24 shipments of prescription drugs transported

1 within the United States that have been deter-
 2 mined to be misbranded or adulterated.”; and

3 (B) in subparagraph (B), by striking “Not
 4 later than 2 years after the effective date of
 5 final regulations under subsection (a),” and in-
 6 serting “Not later than 18 months after the
 7 date of the enactment of the Medicare Prescrip-
 8 tion Drug, Improvement, and Modernization
 9 Act of 2003,”;

10 (9) in subsection (k)(2)—

11 (A) by redesignating subparagraphs (D)
 12 and (E) as subparagraphs (E) and (F), respec-
 13 tively; and

14 (B) by inserting after subparagraph (C)
 15 the following:

16 “(D) The term ‘qualifying individual’
 17 means an individual who is not a pharmacist or
 18 a wholesaler. ”; and

19 (10) by striking subsections (l) and (m).

20 (b) USE OF COUNTERFEIT-RESISTANT TECH-
 21 NOLOGIES TO PREVENT COUNTERFEITING.—

22 (1) MISBRANDING.—Section 502 of the Federal
 23 Food, Drug, and Cosmetic Act (21 U.S.C. 352;
 24 deeming drugs and devices to be misbranded) is
 25 amended by adding at the end the following:

1 “(w) If it is a drug subject to section 503(b), unless
 2 the packaging of such drug complies with the require-
 3 ments of section 505B for counterfeit-resistant tech-
 4 nologies.”.

5 (2) REQUIREMENTS.—Title V of the Federal
 6 Food, Drug, and Cosmetic Act (21 U.S.C. 351 et
 7 seq.) is amended by inserting after section 505A the
 8 following:

9 **“SEC. 505B. COUNTERFEIT-RESISTANT TECHNOLOGIES.**

10 “(a) INCORPORATION OF COUNTERFEIT-RESISTANT
 11 TECHNOLOGIES INTO PRESCRIPTION DRUG PACK-
 12 AGING.—The Secretary shall require that the packaging
 13 of any drug subject to section 503(b) incorporate—

14 “(1) overt optically variable counterfeit-resist-
 15 ant technologies that are described in subsection (b)
 16 and comply with the standards of subsection (c); or

17 “(2) technologies that have an equivalent func-
 18 tion of security, as determined by the Secretary.

19 “(b) ELIGIBLE TECHNOLOGIES.—Technologies de-
 20 scribed in this subsection—

21 “(1) shall be visible to the naked eye, providing
 22 for visual identification of product authenticity with-
 23 out the need for readers, microscopes, lighting de-
 24 vices, or scanners;

1 “(2) shall be similar to that used by the Bureau
2 of Engraving and Printing to secure United States
3 currency;

4 “(3) shall be manufactured and distributed in a
5 highly secure, tightly controlled environment; and

6 “(4) should incorporate additional layers of
7 non-visible covert security features up to and includ-
8 ing forensic capability.

9 “(c) STANDARDS FOR PACKAGING.—

10 “(1) MULTIPLE ELEMENTS.—For the purpose
11 of making it more difficult to counterfeit the pack-
12 aging of drugs subject to section 503(b), manufac-
13 turers of the drugs shall incorporate the technologies
14 described in subsection (b) into multiple elements of
15 the physical packaging of the drugs, including blister
16 packs, shrink wrap, package labels, package seals,
17 bottles, and boxes.

18 “(2) LABELING OF SHIPPING CONTAINER.—
19 Shipments of drugs described in subsection (a) shall
20 include a label on the shipping container that incor-
21 porates the technologies described in subsection (b),
22 so that officials inspecting the packages will be able
23 to determine the authenticity of the shipment. Chain
24 of custody procedures shall apply to such labels and
25 shall include procedures applicable to contractual

1 agreements for the use and distribution of the labels,
 2 methods to audit the use of the labels, and database
 3 access for the relevant governmental agencies for
 4 audit or verification of the use and distribution of
 5 the labels.”.

6 (c) REPEAL.—Subtitle C of title XI of the Medicare
 7 Prescription Drug, Improvement, and Modernization Act
 8 of 2003, and the amendments made by such subtitle, are
 9 repealed.

10 **SEC. 5. ASSURING ACCESS TO COVERAGE.**

11 Paragraph (3) of section 1860D–3(a), as added by
 12 section 101 of the Medicare Prescription Drug, Improve-
 13 ment, and Modernization Act of 2003, is amended to read
 14 as follows:

15 “(3) QUALIFYING PLAN DEFINED.—For pur-
 16 poses of this section, the term ‘qualifying plan’
 17 means a prescription drug plan offered by a PDP
 18 sponsor.”.

19 **SEC. 6. REPEAL OF MA REGIONAL PLAN STABILIZATION**
 20 **FUND.**

21 (a) IN GENERAL.—Section 1858 of the Social Secu-
 22 rity Act, as added by section 221(c) of the Medicare Pre-
 23 scription Drug, Improvement, and Modernization Act of
 24 2003, is amended—

25 (1) by striking subsection (e);

1 (2) by redesignating subsections (f), (g), and
 2 (h) as subsections (e), (f), and (g), respectively; and
 3 (3) in subsection (e), as so redesignated, by
 4 striking “subject to subsection (e),”.

5 (b) CONFORMING AMENDMENT.—Section 1851(i)(2)
 6 of the Social Security Act (42 U.S.C. 1395w–21(i)(2)), as
 7 amended by section 221(d)(5) of the Medicare Prescrip-
 8 tion Drug, Improvement, and Modernization Act of 2003,
 9 is amended by striking “1858(h)” and inserting
 10 “1858(g)”.

11 **SEC. 7. REPEAL OF HEALTH SAVINGS ACCOUNTS.**

12 Section 1201 of the Medicare Prescription Drug, Im-
 13 provement, and Modernization Act of 2003, and the
 14 amendments made by such section, are repealed.

15 **SEC. 8. EFFECTIVE DATE.**

16 (a) IN GENERAL.—The amendments made by this
 17 Act shall take effect as if included in the enactment of
 18 the Medicare Prescription Drug, Improvement, and Mod-
 19 ernization Act of 2003.

20 (b) APPLICATION OF LAWS.—If any amendment to
 21 any provision of any Act is repealed by this Act, such pro-
 22 vision shall be applied and administered as if the amend-
 23 ment had never been enacted.

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